

**510 (K) Summary**

JAN 09 2003

Submitter: Jostra AG  
Hechinger Straße 38  
72145 Hirrlingen  
Germany

Contact Person: Kathleen Johnson  
P. O. Box 218  
Oxford, PA 19363  
Phone: (610) 932-7738  
Fax: (610) 932-7366

Date Prepared: March 08, 2002

Device Trade Name: Jostra Single Stage Venous Return Catheters

Common/Usual Name: Single Stage Venous Catheters

Classification Names: Cardiopulmonary Bypass Vascular Catheter, Cannula and Tubing  
Cariopulmonary Bypass Adaptor, Stopcock, Manifold, or Fitting

Predicate Device: Medtronic DLP Single Stage Venous Cannulae

**Device Description:**

The Jostra Single Stage Venous Catheters are single, sterile devices for single use only and not to be resterilized by the user. The catheters are to be used to divert blood from the patient to the extracorporeal circuit by draining blood from the Inferior Vena Cava and the Superior Vena Cava. The catheters are made from polyvinyl chloride (PVC) and range in size from 12 Fr.- 40 Fr with a variety of tips and with or without attached connectors.

**Indications for use:**

The Jostra Single Stage Venous Return Catheters are designed to be used for the collection of venous blood from the right side of the heart via the superior and inferior vena cava during cardiopulmonary bypass surgery up to 6 hours or less.

**Statement of Technical Characteristics Comparison:**

The Jostra Single Stage Venous Cannulas have the same intended use and design as the Medtronic DLP Single Stage Venous Cannulas. The Jostra Single Stage Venous Cannulas are available in sizes 12 Fr. – 40 Fr. The Medtronic DLP Single Stage Venous Cannulas range in sizes from 12 Fr. – 40 Fr. Comparative testing has demonstrated that the differences do not effect safety and effectiveness.

Non-Clinical Testing:

Biocompatibility and performance testing was performed to demonstrate substantial equivalency to the predicate device.

Performance testing included:

- Flow-Pressure curves
- Kink Resistance
- Bond Strength
- Leakage Test

Additionally, in-vitro testing was performed to determine the effects on cellular components.

Conclusion:

Performance, and in-vitro testing demonstrate that the Jostra Single Stage Venous Return Cannulas are "substantially equivalent" to the predicate devices in intended use, principles of operation, materials, design, and performance.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 09 2003

Jostra AG  
c/o Ms. Kathleen Johnson  
Jostra-Bentley Corp.  
478 Media Road  
Oxford, PA 19363

Re: K020784

Trade Name: Jostra Single Stage Venous Return Catheters  
Regulation Number: 21 CFR 870.4210  
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula and Tubing  
Regulatory Class: Class II (two)  
Product Code: DWF  
Dated: November 20, 2002  
Received: November 22, 2002

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

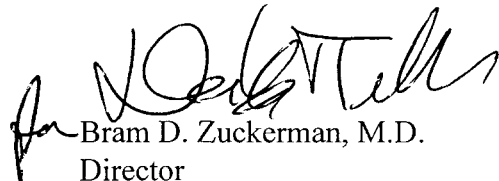
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over the printed name.

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number:

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**Indications for Use**

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

(Optional Format 3-10-98)

  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K020784